# EXHIBIT A

# MARKETING NEURONTIN

Expert Report of Charles King III

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## I. Summary

1. Pfizer Inc. markets and sells the prescription drug Neurontin®. In December 1993, the Food and Drug Administration (FDA) approved Neurontin only for the adjunctive treatment of partial seizures in persons with epilepsy older than 12 years of age at daily dosages up from 900 mg to 1800 mg. Parke-Davis Pharmaceuticals started selling Neurontin in January 1994. Neurontin subsequently received additional FDA approvals for use as adjunctive therapy for treatment of seizures in children (October 2000) and for the management of post-herpetic neuralgia in adults (May 2002). Pfizer acquired Warner-Lambert LLC (Warner-Lambert) and its Parke-Davis division in 2000.

2. I have been retained by counsel to address certain marketing and economic issues with respect to the off-label promotion of Neurontin.

3. It is my understanding that it is illegal for drug companies to promote drugs for other, so-called "off-label," uses that do not have FDA approval. I also understand the following. Beginning in the mid-1990s, Neurontin was heavily promoted and widely used for the off-label treatment of pain syndromes and psychiatric conditions, including bipolar disorder. In 2004, Warner-Lambert, the original developer of Neurontin, admitted guilt and settled litigation charging that during the 1990s Warner-Lambert violated federal regulations by promoting Neurontin for pain, psychiatric conditions, migraine, and other unapproved uses. Since acquiring Warner-Lambert in 2000, Pfizer has continued to promote Neurontin for these and other unapproved uses. Pfizer has failed to disclose the lack of efficacy of Neurontin for certain off-label uses, suppressed information about its serious adverse events, and made false and misleading statements about Neurontin and its unapproved uses.

4. On the basis of the above understanding of facts, counsel has retained me to provide an expert opinion with respect to four main questions:

a. Were the marketing and promotional efforts of Warner-Lambert and Pfizer significant contributing factors to the off-label sales of Neurontin?

b. Would significant off-label sales of Neurontin have continued had Pfizer ceased off-label promotional activities for Neurontin?

c. Did the suppression of information about serious adverse events enable growth in off-label sales?

d. Did Pfizer's off-label marketing of Neurontin indirectly influence all physicians prescribing of Neurontin?

5. In response to these questions, it is my opinion that:

a. The marketing and promotional efforts of Warner-Lambert and Pfizer were significant contributing factors to the off-label sales of Neurontin.

b. Off-label sales of Neurontin would have continued had Pfizer ceased off-label promotional activities for Neurontin.

c. The suppression of information about serious adverse events enabled growth in off-label sales.

d. Pfizer's off-label marketing of Neurontin indirectly influenced all, or substantially, all physicians prescribing of Neurontin.

## II. Qualifications

6. I am a Special Consultant to Greylock McKinnon Associates, a consulting and litigation support firm located in Cambridge, Massachusetts. As an economist, I specialize in marketing, industrial organization, microeconomics and econometrics.

7. I have taught economics, marketing and statistical methods in economics; conducted marketing and economic research; and provided economic and marketing consulting in my areas of specialization. As an Assistant Professor in Marketing at the Harvard Business School from 1997 to 2003, I taught courses in marketing, information and network economics, and organizational economics in the Masters and Doctoral programs. I also taught in Harvard Business School's executive education program for pharmaceutical companies and in IBM's Premier Program on competitive strategy. Since 1981, I have consulted to private corporations, nonprofit corporations, law firms, consulting companies and research organizations. Since 2001, I have served as a member of the Editorial Review Board for *Journal of Public Policy & Marketing*. I have been and continue to be a research referee for a variety of academic journals and the Robert Wood Johnson Foundation. I am the author of various refereed journal articles, working papers and consulting reports.

8. My research activities include issues concerning health care and the pharmaceutical industry. For example, I have written an academic working paper[1] analyzing marketing, product differentiation and competition in the pharmaceutical drug market at issue in this case and published a case study[2] evaluating Pepcid's race against Zantac and other competitors to enter the over-the-counter market. I have published a variety of peer-reviewed articles and cases,[3] including applications of marketing and economic analyses to health care and pharmaceutical issues.

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[1] C. King, "Marketing, Product Differentiation and Competition in the Market for Antiulcer Drugs," Harvard Business School, Working Paper No. 0-014 (Sept. 2000).

[2] E.R. Berndt, C. King, L. Klein and A.J. Silk, "Pepcid AC: The Race to Enter the OTC Market," (9-500-073), Harvard Business School. Also published in *Problems and Cases in Health Care Marketing*, edited by J.T. Gourville, J.A. Quelch and V.K. Rangan, McGraw-Hill Irwin, 2003.

[3] *See* C. King and D. Narayandas, "Coca-Cola's New Vending Machine (A): Pricing To Capture Value, or Not?" (9-500-068), Harvard Business School; E.R. Berndt, C. King, L. Klein and A.J. Silk, "Pepcid AC: The Race to Enter the OTC Market," (9-500-073), Harvard Business School (also published *in Problems and Cases in Health Care Marketing*, edited by J.T. Gourville, J.A. Quelch and V.K. Rangan. McGraw-Hill Irwin, 2003).

can affect the course of an illness. This problem is exacerbated for Neurontin because many of the "off-label" uses of Neurontin have large "placebo effects".[76] As a result, market forces are likely to fail to protect consumers against false drug claims.

## VI. Marketing Neurontin in the Warner-Lambert Era (1994 – 2000)

### A. Creation of the Off-Label Strategy

37. Neurontin was initially approved only for epileptic seizures in adult patients who had failed to improve using other treatments, a limited market.[77] Yet Neurontin became a one of the world's best-selling drugs, as sales for unapproved uses grew to approximately 90 percent of sales (See Figure 8).[78] Off-label uses for Neurontin grew from approximately 15 percent of all uses in 1994 when Neurontin was first marketed to 94 percent of all uses in the United States by 2002.[79]

**Figure 8: Neurontin Sales for Unapproved Uses Were Approximately 90 Percent of Total Sales in 2003.**

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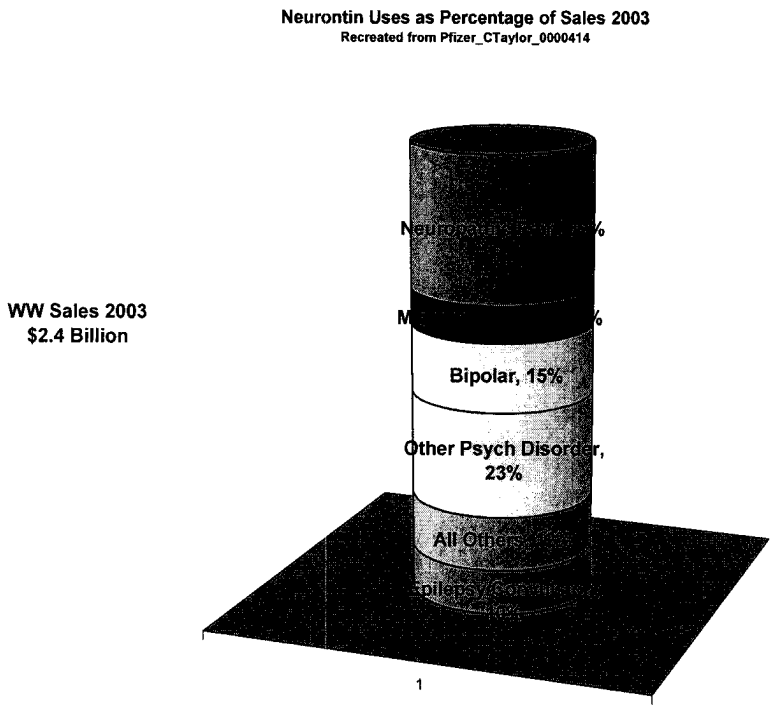
[76] The placebo effect is defined as: "A remarkable phenomenon in which a placebo -- a fake treatment, an inactive substance like sugar, distilled water, or saline solution -- can sometimes improve a patient's condition simply because the person has the expectation that it will be helpful." MediceNet.com (http://www.medterms.com/script/main/art.asp?articlekey=31481) Placebo effects are widespread in clinical research and practices and have been widely studied. See, for example, Fabrizio Benedetti and Martina Amanzio, "The Neurobiology of Placebo Analgesia: From Endogenous Opiods to Cholecystokinin," *Progress in Neurology*, Vol. 51, pp. 109-125, 1997; Frederic M. Quitkin, "Placebos, Drug Effects, and Study Design: A Clinician's Guide," *American Journal of Psychiatry*, 156:6, June 1999 (placebo response rates vary from 25 to 60% for patients with major depressive disorders); Asbjorn Hrobjartsson and Peter Gotzche, "Is the Placebo Powerless? An Analysis of Clinical Trials Comparing Placebo with No Treatment," *The New England Journal of Medicine*, Vol. 344, No. 21, May 24, 2001 (review of 27 trials involving pain treatment "showed a significant effect of placebo as compared with no treatment"); Marlena A. Piercy, John J. Sramek, Neal M. Kurtz and Neal R. Cutler, "Placebo Response in Anxiety Disorders," *The Annals of Pharmacotherapy*, Vol. 30, No. 9, 1996, pp. 1013-1019 (summarizes placebo response rates: generalized anxiety, 18-67%; panic disorders, 20-134%; social phobia, 7-43%; and obsessive-compulsive disorder, 7-19%).

[77] See ¶¶ 12 and 16.

[78] In 2003, Neurontin ranked 10th in U.S. sales (Drugs.com, http://www.drugs.com/top200_2003.html) with sales of $2.4 billion.

[79] Sentencing Memorandum of the United States, p. 13.




38. Warner-Lambert promoted Neurontin for the treatment of bipolar disorder, a psychological condition, even though a study had shown that the medicine was no better than a placebo in treating the disorder.[80] Other disorders for which Neurontin was illegally promoted included various pain disorders, anxiety disorder, social phobias, amyotrophic lateral sclerosis (ALS, a degenerative nerve disease commonly referred to as Lou Gehrig's disease), attention deficit disorder, migraine, drug and alcohol withdrawal seizures, restless leg syndrome, and as a first-line monotherapy treatment for epilepsy (using Neurontin alone, rather than in addition to another drug).[81]

39. Warner-Lambert executives started exploring ways to expand the market for Neurontin beyond the scope of its initial FDA approval soon after its

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[80] Pande AC, Crockatt JG, Janney CA, Werth JL, Tsaroucha G. Gabapentin in bipolar disorder: a placebo-controlled trial of adjunctive therapy. Gabapentin Bipolar Disorder Study Group. Bipolar Disord. 2000;2:249-55. [PMID:11249802].

[81] Sentencing Memorandum of the United States, Section E; Information, *united States of America v. Warner-Lambert Company LLC*, United States District Court, District of Massachusetts, May 13, 2004 (hereafter "Information") ¶¶ 8 - 10.

B. Health & Human Services Determinations that Pfizer's Representations About Neurontin Are False And Misleading

66. An example of Pfizer's inappropriate, off-label promotion of Neurontin was identified by the FDA's Division of Drug Marketing, Advertising and Communications (DDMAC).[155] On July 1, 2002, Dr. Lisa L. Stockbridge, PhD., a Regulatory Reviewer at DDMAC, notified Pfizer that certain Neurontin marketing material was "in violation of the Federal Food, Drug and Cosmetic Act . . . because [Pfizer] makes representations about Neurontin that are false and misleading."[156] Specifically, DDMAC objected to Pfizer marketing material suggesting 1) that the mechanism of action of Neurontin in the human brain had been established when this was false, as the mechanism by which Neurontin worked was unknown; 2) that "Neurontin is useful for a broader range of CNS [central nervous system] conditions that has been demonstrated by substantial evidence"; and 3) that "Neurontin can be used as monotherapy for various CNS disorders" when Neurontin was only approved as adjunctive therapy in the treatment of partial seizures and adult and pediatric patients.[157] Because these representations about Neurontin were false or misleading, DDMAC requested that Pfizer "[i]mmediately discontinue the use of [these] and any other promotional material with the same or similar issues."[158]

## VIII. Effects of Neurontin Off-Label Marketing Strategy

67. Even if Pfizer had done nothing to promote unapproved uses of Neurontin after it acquired Warner-Lambert, sales of Neurontin for unapproved uses would have continued. Successful marketing, in general, and pharmaceutical marketing, in particular, has long term effects. The creation of a successful brand image leads to sales even after promotion stops.

A. Marketing Effects Are Long-Lived

1. Evidence from Academic Studies

68. The effect of marketing on drug sales has been widely studied over the years. Empirical studies have investigated the responsiveness of drug sales to

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[155] Lisa Stockbridge Letter, dated July 1, 2002, Pfizer_LCastro_0074739-40. For another example, see Lisa Stockbridge Letter, dated June 29, 2001, Marino Exhibit 45, Pfizer_RGlanzman_0054596-609.

[156] Lisa Stockbridge Letter, dated July 1, 2002, Pfizer_LCastro_0074739-40.

[157] Ibid.

[158] Ibid. at Pfizer_LCastro_0074740.